omnipod®

INSULIN MANAGEMENT SYSTEM

Podder's handbook™

ENT450

USER GUIDE

3 DAYS* NONSTOP INSULIN

*Up to 72 hours of insulin delivery

Appendix

Summary of Settings and Options

The options for the various Omnipod® Insulin Management System settings are:

Time	12-hour or 24-hour clock
Date	MM/DD/YY DD/MM/YY MM.DD.YY DD.MM.YY YY-MM-DD
Maximum Basal Rate	0.05-30 U/hr. Default is 3.00 U/hr
Basal rate	U/hr. Range: 0.05 U/hr to Maximum Basal Rate in 0.05 U/hr increments.
Basal Programs	7
Basal rate segments	24 per program
Temp basal	%, U/hr, or Off. Default is Off Duration: 30 min to 12 hrs in 30-min increments
Temp basal (set to %)	Range: 0 U/hr ("Off") to 95%MORE of current basal rate in 5% increments. Cannot exceed Maximum Basal Rate.
Temp basal (set to U/hr)	Range: 0 0 U/hr ("Off") to Maximum Basal Rate
Temp basal presets	7
BG Goal Range for blood glucose history	Lower and upper limits: 3.9 to 11.1 mmol/L in 0.1 mmol/L increments
BG reminder	On or Off. Default is Off. Maximum of 4 active at one time Reminder can occur between 30 min to 4 hrs after bolus is started. Set in 15-minute increments.
Custom reminder	Maximum of 4. Set to Daily, One time only, Off
BG Meter sound	On or Off. Default is On.
Bolus Calculator	On or Off. Default is On.
Target BG value	8 time segments; 3.9 to 11.1 mmol/L in 0.1 mmol/L increments
Correct Above threshold	8 time segments; Target BG to 11.1 mmol/L in 0.1 mmol/L increments
Minimum BG for Calcs	2.8 to 3.9 mmol/L in 0.1 mmol/L increments Default is 3.9 mmol/L

Insulin-to-carb (IC) ratio	8 time segments; 1 to 150 g carb/U in 1g carb/U increments
Correction (sensitivity) factor	8 time segments; 0.1 to 22.2 mmol/L in 0.1 mmol/L increments
Reverse correction	On or Off. Default is On.
Duration of insulin action	2 to 6 hours in 30-minute increments
Bolus increment	0.05, 0.1, 0.5, or 1.0 U. Default is 0.1 U
Maximum Bolus size	0.10-30U in 0.05U increments. Default is 10 U.
Extended bolus	%, Units, or Off. Default is Off 30 minutes to 8 hours in 30-minute increments
Bolus preset	Max of 7. Cannot exceed the Maximum Bolus.
Carb preset	Max of 36. Range: 0-300 g
Suspend	30 minutes to 2 hours
Low reservoir volume advisory	10 to 50 U in 5-unit increments. Default is 10.0 U
Pod expiration notification	1 to 24 hours in 1-hour increments. Default is 4 hours
Auto-off timer	Off, or 1 to 24 hours in 1-hour increments. Default is Off
PDM lock	On or Off. Default is Off
History storage	5400 records/90 days

Pod Specifications

Size: 3.9cm wide x 5.2cm long x 1.45cm high (1.53" x 2.05" x 0.57")

Weight (without insulin): 25 grams (0.88 oz)

Operating temperature range: Pod operating environment of 4.4°C to 40°C (40°F to 104°F).

> **Note:** The Pod temperature equilibrates to 22.7°C to 37°C (73°F to 98.6°F) when worn on the body.

Startup temperature: above 10°C (50°F)

Storage temperature range: 0°C to 30°C (32°F to 86°F)

Reservoir volume (deliverable): 200 U

Cannula insertion depth: 0.16-0.28 in (4-7 mm)

Depth of insulin infusion: ≥ 0.16 in (4 mm)

Waterproof rating: IP28 (7.6 meters (25 feet) for up to 60 minutes)

Insulin concentration: U-100

Alarm type: Audible. Output: ≥ 45 db(A) at 1 meter

Operating relative humidity range: 20 to 85%, non-condensing

Storage relative humidity range: 20 to 85%, non-condensing

Operating atmospheric pressure: 696 hPA to 1060 hPA

Storage atmospheric pressure: 696 hPA to 1060 hPA

Non-pyrogenic: Fluid pathway only

Type BF applied part: Protection from electrical shock

Maximum infusion pressure: 35 psi

Maximum volume infused under single fault conditions: 0.0 U

Flow Capability:

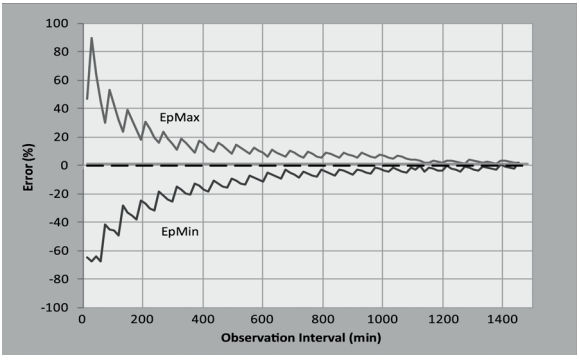
Basal: Programmable by the user in 0.05U increments up to 30.0 U per hour
Bolus: Rate: 1.5 U per minute. Dose range from 0.05 to 30.0 U

Delivery accuracy (tested per IEC 60601-2-24):

Basal: ± 5% at rates ≥ 0.05 U/hr
Bolus: ± 5% for amounts ≥ 1.0 unit
± 0.05 units for amounts < 1.0 unit

One Pod was tested at each configuration.

Accuracy test results: The following graph shows the flow accuracy of the Pod against given time periods. The measurements were made using a Pod with a basal rate of 0.05 U/h at high operating temperature. The overall mean percentage flow error was 1.40%.



PDM Specifications

Size: 6.21 cm wide x 11.25 cm long x 2.5 cm high (2.4" x 4.4" x 0.98")

Weight: 125 grams (4.41 oz)

Screen: 3.6 cm wide x 4.8 cm long (1.4" x 1.9"); 6.1 cm diagonal (2.4") LCD

Battery: Powered by 2 AAA batteries

Battery life: Approximately 3 weeks

Operating temperature range: 4.4°C to 40°C (40°F to 104°F)

Storage temperature range: -29°C to 60°C (-20.2°F to 140°F)

Operating relative humidity range: 15% to 90% non-condensing

Storage relative humidity range: 10% to 90% non-condensing

Operating atmospheric pressure: 696 hPA to 1062 hPA

Storage atmospheric pressure: 703 hPA to 1062 hPA

Communication distance: The PDM and Pod should be

- At startup: Adjacent and touching, either in or out of tray, to ensure proper communication during priming.
- During normal operation: Within 1.5 m (5 feet) of each other.

Waterproof rating: IP22 (avoid liquid)

Alarm type: Audible. Output: ≥ 50 db(A) at 1 meter

Notification type: Audible and vibratory

Built-in BG Meter Specifications

Assay method: Coulometric electrochemical sensor

Calibration: Plasma equivalent

Hematocrit: 15% to 65%

Measurement units: mmol/L

Result range: 1.1 to 27.8 mmol/L

Sample: Whole blood, capillary

Sample size: 300 nanoliters (0.3 microliters)

Test time: Results obtained in 7 seconds or less

Protection from Over-infusion or Under-infusion

The Pod software monitors the infusion rate. If an error that would result in over- or under-infusion is detected and cannot be corrected, insulin delivery stops, and an alarm sounds.

Occlusion detection

An occlusion is a blockage or interruption in insulin delivery. If the Omnipod® System detects an occlusion, it sounds a hazard alarm and prompts you to deactivate and change your Pod.

A hazard alarm sounds when an average of 3 U to 5 U of missed insulin occurs. The following table depicts occlusion detection for three different situations when using U-100 insulin. For example, if the Pod's cannula becomes occluded when delivering a 5 U bolus, between 153 seconds and 35 minutes may pass before the Pod sounds a hazard alarm.

	Time between occlusion and Pod alarm	
	Typical time	**Maximum time**
5.00 U bolus	33 minutes	35 minutes
1.00 U/hr basal	3.0 hr	5.5 hr
0.05 U/hr basal	51 hr	80 hr (Pod expiration)

If an occlusion spontaneously clears up, a volume of insulin could be released. That volume would not exceed the volume of the programmed insulin intended for delivery.

If an occlusion is detected during a bolus, the Pod sounds a hazard alarm at the conclusion of the bolus.

Warning: At very low flow rates, checking your blood glucose frequently may give you an early indication of an occlusion.

System Accuracy according to International Standard ISO 15197:2013

Capillary blood glucose results were compared with those obtained using the YSI Glucose Analyser.

System accuracy for finger samples with YSI glucose results lower than 5.55 mmol/L and 27.8 mmol/L.

Within ± 0.3 mmol/L	Within ± 0.6 mmol/L	Within ± 0.8 mmol/L
141/201 (70.1%)	192/201 (95.5%)	200/201 (99.5%)

System accuracy for finger samples with YSI glucose results of 5.55 mmol/L or higher.

Within ± 5 %	Within ± 10 %	Within ± 15%
323/483 (66.9%)	440/483 (91.1%)	477/483 (98.8%)

System accuracy for glucose concentrations between 2.22 mmol/L and 27.8 mmol/L.

Within ± 0.83 mmol/L or ± 15%
677/684 (99.0%)

A study* evaluating glucose values from fingertip capillary blood samples obtained by 590 lay persons showed the following results:

98.1% within ±0.83 mmol/L of the YSI reference at glucose concentrations below 5.55 mmol/L, and 98.4% within ±15% of the YSI reference at glucose concentrations at or above 5.55 mmol/L.

*Data on file at Insulet Corporation

PDM Icons

This section defines the images found on the PDM screens.

Icon	Meaning	Icon	Meaning
	Home/Power		More actions
	Bolus		Communication
	Pod change		Up/Down
	Diagnostics/ settings		Up/Down (on color)
	Temp basal		Status
	Suspend/cancel		Text entry right
	Basal Program		Submenu
	Hazard alarm (Alternating/ flashing image)		Home screen
	Advisory alarm		Apply blood sample/ Blood glucose records
	Alert		Insulin gauge
	Battery full		Setup Wizard
	Battery 3/4 full		PDM lock
	Battery 1/2 full		Information/ Support
	Battery 1/4 full		My records
	Battery empty		"Lost" history record

Icon	Meaning
◆	Active/default program or selected BG tag
	Built-in BG meter temperature out-of-range

Icon	Meaning
	"Delivery Spans Midnight" history record
✓	"Unconfirmed" history record

Omnipod® System Label Symbols

The following symbols appear on the Omnipod® System or its packaging:

Symbol	Meaning
	Single Use
	Consult instructions for use or consult electronic instructions for use
	Follow instructions for use
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system
	Date of manufacture
LOT	Batch code
	Use by date
REF	Reference number
SN	Serial number
IP28	Submersible to 7.6 meters (25 feet) for up to 60 minutes

Symbol	Meaning
	MR Unsafe
	Non-pyrogenic fluid path
	Do not use if package is damaged
	Type BF applied part
	Manufacturer
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
MD	Medical device
IP22	Avoid liquid

Symbol	Meaning
EC REP	Authorized Representative in the European Community
CE	Marking of conformity
	Importer
	(France) The puncture waste must be placed in a DASTRI needle box. These needle boxes are distributed by pharmacies.
	Do not dispose with household waste
	(France) All pharmacies distribute and collect DASTRI needle boxes free of charge from self-treatment patients.
	(France) Packaging intended for recycling

Symbol	Meaning
CH REP	Switzerland Authorized Representative
UK CA 0086	UK Conformity Assessed
	(France) This product must be separated from conventional perforating DASTRI for recycling.
	(France) Electronic perforating waste must be stored in the secure DASTRI purple box. These purple boxes are distributed free of charge in pharmacies.
	(France) The Triman indicates that the product must be sorted or returned to a collection point.
	(France) This pictogram means that the product contains a piercing object.

Medical Device Directive

This device complies with Medical Device Directive 93/42/EEC.

Contact Person: The Complaints Officer

Address: Insulet Netherlands B.V., WTC Utrecht Stadsplateau 7, Suite 7.06, 3521 AZ Utrecht, The Netherlands

TEL: +31 308 990 670

E-mail: ECRep@insulet.com

Omnipod® System Notice Concerning Interference

The Omnipod® Insulin Management System (both the Pod and the PDM) complies with Part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions:

1. These devices may not cause harmful interference.
2. These devices must accept any interference received, including interference that may cause undesirable operation.

Changes or modifications not expressly approved by Insulet Corporation could void the user's authority to operate the equipment.

Both the Pod and the PDM generate, use, and can radiate radio frequency energy, and may cause harmful interference to radio communications of other devices. There are no guarantees that interference will not occur in a particular installation. If the Omnipod® System does cause harmful interference to radio and television reception, the interference may be corrected by one of the following measures:

- Move or relocate the Omnipod® System.
- Increase the distance between the Omnipod® System and the other device that is emitting or receiving interference.

Insulet Corporation declares that the Omnipod® System is in compliance with the essential requirements and other relevant provisions of Radio Equipment Directive (2014/53/EU). The full Declaration of Conformity can be found at the following web address: http://omnipod.com/Red_Doc

This ISM device complies with Canadian ICES-003 and IC-RSS-210.

Electromagnetic Compatibility

The information contained in this section (such as separation distances) is, in general, specifically written with regard to the Omnipod® System. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the instructions for use. If the Omnipod® System fails due to electromagnetic disturbances, you may need to replace it.

Portable and mobile radio frequency (RF) communications equipment can affect the function of medical electrical equipment.

Insulet Corporation declares that the Omnipod® Insulin Management System is in compliance with the essential requirements and other relevant provisions of Radio Equipment Directive (2014/53/EU). The full Declaration of Conformity can be found at the following web address:

http://omnipod.com/Red_Doc

> **Warning:** Cables and accessories not specified within the instructions for use are not authorized. Using other cables or accessories may adversely impact safety, performance, and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the Omnipod® System is used adjacent to other electrical equipment; if adjacent use is inevitable, such as in work environments, the Omnipod® System should be observed to verify normal operation in this setting.

The Omnipod® System communicates by low level RF energy. As with all RF receivers, the potential for disturbance exists, even with equipment that complies with FCC and CISPR emissions requirements.

The Omnipod® System communicates with the following characteristics:

Frequency: 433 MHz, FSK modulation, with an effective radiated power of 3 dBm

The Omnipod® System complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that is used in such an environment.

Emissions	Compliance according to	Electromagnetic environment
RF Emissions (CISPR 11)	Group 2	The Pod and the PDM emit low level electromagnetic energy (RF) in order to communicate. Although unlikely, nearby electronic equipment may be affected.
CISPR B Emissions Classification	Class B	The System is suitable for use in all establishments including domestic establishments.

Electromagnetic Immunity

The System is intended for use in the electromagnetic environment specified below. You should observe these requirements in the use of the System.

Immunity against	IEC 60601-1-2 test level	Compliance level (of this device)	Electromagnetic environment
ElectroStatic Discharge, ESD (IEC 61000-4-2)	contact discharge: ± 6 kV air discharge: ± 8 kV	± 8 kV ± 15 kV	If floors are covered with synthetic material, try to avoid electrostatic discharges.
Power frequency magnetic fields 50/60 Hz (IEC 61000-4-8)	3 A/m	400 A/m	Suitable for most environments. Magnetic field strengths in excess of 400 A/m would be unlikely except in close proximity to industrial magnetic devices.
Radiated RF (IEC 61000-4-3)	80 MHz–2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as below. Recommended separation distance: $d=1.17\sqrt{P}$ 150 KHz to 80 MHz $d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.

Electromagnetic Immunity

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

You can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, in watts	**Separation distance according to frequency of transmitter, in meters**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	*80 MHz to 800 MHz* $d = 0.35\sqrt{P}$	*800 MHz to 2.5 GHz* $d = 0.7\sqrt{P}$
0.01	0.12	0.035	0.070
0.1	0.37	0.11	0.22
1	1.17	0.35	0.7
10	3.70	1.11	2.21
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Warranty for the PDM and Pods

WARRANTY FOR THE OMNIPOD® INSULIN MANAGEMENT SYSTEM PERSONAL DIABETES MANAGER AND PODS (United Kingdom and Ireland)

WARRANTY COVERAGE

Warranty Coverage for the Omnipod® System Personal Diabetes Manager

Subject to the terms and conditions below, Insulet International Limited ("Insulet") warrants to you, the original recipient of the Omnipod® Insulin Management System ("Omnipod® System"), that, if Insulet determines that your Personal Diabetes Manager ("PDM") has a defect in material or workmanship while utilized under normal use and conditions during the period of four (4) years from the date of purchase (or receipt where purchased on your behalf), Insulet will either repair or replace, at its sole option, the PDM.

This four-year (4) warranty period applies only to new PDMs and, in the event the PDM is repaired or replaced, the warranty period shall not be extended or reset.

Warranty Coverage for the Omnipod® System Pods

Subject to the terms and conditions below, Insulet warrants to you, the original recipient of the Omnipod® System, that if Insulet determines that an Omnipod® System Pod ("Pod") you have received has a defect in material or workmanship while utilized under normal use and conditions during the period of eighteen (18) months from the date of manufacture and seventy-two (72) hours from the time of activation, Insulet will either repair or replace, at its sole option, that Pod. To be eligible for replacement, the activation of the Pod must fall within both time periods (i.e. occur on or before the expiration date printed on the label with a manufacture date no more than eighteen (18) months before and on or before a time no more than seventy-two (72) hours before you notify Insulet of the claim).

This eighteen (18) month and seventy-two (72) hour warranty period applies only to new Pods and, in the event a Pod is repaired or replaced, the warranty period shall not be extended or reset.

WARRANTY TERMS AND CONDITIONS

This Warranty applies only to PDMs and Pods that were originally sold for use in United Kingdom or Ireland (the "Territory"). Insulet will only ship repaired or replaced PDMs and Pods and provide Warranty services within the Territory.

Claim Procedure

To be eligible to claim under this Warranty, you must notify Insulet of the claimed defect with the PDM or the Pod within the applicable warranty period by calling Customer Care at:

- From the UK: 0 800 011 61132
- From Ireland: +44 800 011 6132

For a claim involving the PDM, you must provide the PDM serial number and a description of the claimed defect. For a claim involving a Pod, you must provide the Pod lot number and a description of the claimed defect. You may also be required to verify the date of purchase (or receipt where purchased on your behalf) of the PDM and/or the Pod and the time that you activated the Pod.

Your failure to follow any of the above steps may result in the denial of coverage under this Warranty.

Unless Insulet elects to repair the Pod or the PDM (which may include, but is not limited to, a repair kit or replacement part(s) Insulet provides) or refers you to a third party repairer, you must obtain Insulet's authorization prior to returning the Pod or the PDM to Insulet. The Pod or PDM must be properly packaged and returned to Insulet according to the instructions provided in the Return Merchandise Authorization, or RMA, Kit, which will be sent to you by Insulet. With a prior authorization, Insulet will pay all reasonable packaging and postage charges, where applicable, incurred in shipping the Pod or the PDM to Insulet under this Warranty. For the avoidance of doubt, this Warranty does not cover repairs performed or replacements provided by any person or entity other than Insulet, except those performed or provided by third parties to which you were explicitly referred by Insulet.

Proof of Purchase, Receipt or Activation

In order to verify the date of purchase (or receipt where purchased on your behalf) or, in the case of a Pod, the time of activation and determine if the claim under this Warranty is within the applicable warranty period, Insulet may require that you provide a valid proof of purchase, receipt or activation. Your failure to provide valid proof, as determined by Insulet, may result in the denial of coverage under this Warranty.

Exclusions

This Warranty covers only the original recipient and you cannot transfer or assign it with the sale, rental or other transfer of the PDM or of the Pods to any other person or entity.

This Warranty will apply only if the PDM or the Pod at issue has been used in accordance with the Omnipod® System User Guide and/or other written instructions provided by Insulet. This Warranty does not apply if the PDM or the Pods have been:

- Altered, changed or modified by any person or entity other than Insulet or third party authorized by Insulet;

- Opened, serviced or repaired by any person or entity other than Insulet or third party authorized by Insulet;
- Damaged by an act of God or other "force majeure" like event;
- Damaged by misuse, abuse, negligence, accident, unreasonable use, or improper handling, care or storage;
- Damaged by wear and tear, causes unrelated to defective materials or workmanship (including without limited unsuitable or faulty batteries) or other circumstances outside of the reasonable control of Insulet.

This Warranty does not apply to, test strips, batteries, other accessories or related products provided by third parties (e.g., data management tools, CGMs).

This Warranty does not extend to design defects (i.e., claims that the PDM or the Pods should have been designed in a different way).

Disclaimer of Implied Warranties and Limitation of Remedies

To the extent permitted by law in your country of residence:

- **This Warranty and the remedies set out in it are the only warranties and remedies provided by Insulet to you in relation to the PDM and the Pods and all other statutory and implied warranties are expressly excluded to the maximum extent permitted.**
- **Insulet, its suppliers, distributors, service providers, and/or agents will not be liable for indirect, special, incidental or consequential damages caused by a defect in the PDM or a Pod or by a breach of this Warranty, whether such claim is based in warranty, contract, tort or otherwise.**

Nothing in this Warranty is intended to exclude our liability for death or personal injury resulting from our negligence, for fraud or fraudulent misrepresentation, or for breach of your statutory rights in relation to the PDM or Pods.

Important Additional Provisions

This Warranty gives you specific legal rights. You may also have other statutory rights which vary by jurisdiction.

Your statutory rights are not affected by this Warranty.

Insulet does not warrant the suitability of the PDM or the Pods or the Omnipod® System for any specific person as health care and treatment are complex subjects requiring the services of qualified health care providers.

This Warranty is between you and Insulet. No other party has any rights to enforce any of its terms. Insulet may transfer its rights and obligations under this Warranty to another party without your consent.

If any provision of this Warranty is found to be invalid by any court that provision will be deemed to be deleted from this Warranty and the validity of the remaining provisions will not be affected.

No Other Warranty or Agreement

Unless modified in writing and signed by both Insulet and you, the terms set out in this Warranty are the complete and exclusive understanding between Insulet and you, superseding all prior warranties and agreements, oral or written, and all other communications relating to any defect in, failure or other malfunction in a PDM, a Pod, or an Omnipod® System. No employee, agent or other representative of Insulet or any other party is authorized to make any product warranty or agreement applicable to a PDM, a Pod, or an Omnipod® System in addition to those made in the foregoing.

Consent to Disclaimer of Implied Warranties and the Limitation of Remedies

If you do not consent to and instead wish to reject the Disclaimer of Implied Warranties and the Limitation of Remedies included along with the Omnipod® System, please return any Omnipod® System products (including any PDM and Pod) to Insulet in exchange for a full refund. Failure to return such products shall constitute acknowledgement of and consent to the Disclaimer of Implied Warranties and the Limitation of Remedies.

Governing Law and Jurisdiction

This Warranty (and any non-contractual obligations arising out or in connection with it) is governed by the laws of your country of residence. Any court of competent jurisdiction in your country of residence will have exclusive jurisdiction and venue for any dispute arising out of or in connection with this Warranty.

Rev: July, 2018

omnipod®

INSULIN MANAGEMENT SYSTEM

Insulet Corporation
100 Nagog Park
Acton, MA 01720 USA

Support/Supplies: 0800 011 6132 | Omnipod-GB@insulet.com

omnipod.com

Welcome, Podder™!

PDM imagery is for illustrative purposes only.
PDM screens may vary based on model or user settings.

Model: ENT450

**IP28 up to 25 feet for 60 minutes – PDM not waterproof

17845-5C-AW Rev 05 05/24

17845-5C

CE 2797